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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,815	12/07/2000	Akira Aomatsu	5836-01-MJA	5030

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05/30/2002

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EXAMINER

KWON, BRIAN YONG S

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 05/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,815

Applicant(s)

AOMATSU, AKIRA

Examiner

Brian S Kwon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

B DETAILED ACTION

Status of Application

By amendment filed February 12, 2002, Claims 1-9 have been amended and Claims 18-22 have been newly added. Claims 1-9 and 18-22 are currently pending.

Summary of Action

- I. The objection of claims 4-9 will not be maintained in light of the amendment.
- II. The rejection of claims 1-9 under 35 USC 112, second paragraph, will not be maintained in light of the amendment.
- III. The rejection of claims 1-6 and 9 under 35 USC 102(b) as being anticipated by Woodruff (US 5084479) will not be maintained in light of the amendment.
- IV. Claims 2-9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.
- V. Claims 19-22 are rejected under 35 USC 112, second paragraph.
- VI. Claims 1-6, 9 and 18-20 are rejected under 35 USC 102(b) as being anticipated by Woodruff (US 5084479).
- VII. Claims 2-8 are rejected under 35 USC 102(b) as being anticipated by Robson (US 4126684).

Claim Objection

Claims 2-9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel

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the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 1 recites that the alpha-amino acid is not glycine. In other words, the applicant excludes glycine and 4-amino-3-substituted-butanoic acid derivative combination by reciting such negative proviso in claim 1. However, dependent claims 2-9 still recite glycine as alpha-amino acid. The scope of dependent claims 2-9 appears to be broader than parent claim 1, failing to further limit the subject matter of a previous claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is vague and unclear by reciting "the α amino acid is as provided in Claims 2 or 3". As discussed in preceding comments (Claims 2-9 Objection), due to improper dependent form of Claims 2-3, it is unclear of the scope of the present invention (Claims 19-22) encompasses glycine as alpha-amino acid. Applicant is requested to clarify.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9 and 18-20 are rejected under 35 USC 102(b) as being anticipated by Woodruff (US 5084479).

Woodruff discloses a solution comprising N-methyl-D-aspartic acid and gabapentin (column 8, line 5).

Claims 2-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Robson et al. (US 4126684).

Robson et al teaches a composition comprising baclofen and glycine in various dosage forms including tablets, capsules or suppositories or injection (see Example 2; column 3, line 54 thru column 4, line 11).

It is noted to applicant that recitation of inherent property such as the use of glycine as a stabilizing agent is not limited to the interpretation of composition claim.

Response to Arguments

Applicant's arguments filed February 12, 2002 have been fully considered but they are not persuasive.

Applicant's argument takes position that "Woodruff does not disclose a solution, let alone a composition comprising gabapentin and glycine. This assertion is supported by Figure 3A-B of Woodruff. . . In the third signal from the left, there are two solid bars, indicating the injection of (1) 1 μ M glycine and 10 μ M strychnine and (2) 10 μ M gabapentin. Thus, Figure 3B qualifies as proof that Woodruff does not disclose a gabapentin-glycine composition".

Applicant's arguments with respect to claims 1-6 and 9 have been considered and found persuasive. However, they are moot in view of the new ground(s) of rejection.

Applicant's argument takes position that "the disclosed purpose of the Robson invention is to prevent future addiction or to ameliorate the withdrawal symptoms in the addicted by using a combination of an addicting agent with a 4-amino-3-p-halophenyl-butyric acid". The examiner disagrees. It is noted to applicant that claims to a composition possessing a particular property or characteristic are still properly rejected by a reference to the same composition, even if the reference does not address or acknowledge the property. The property or characteristics is deemed to be inherent to the composition, i.e., it was always there.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703)308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

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